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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,156	08/07/2003	Charles Signorino	920-2	3587

27758 7590 10/06/2005

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EXAMINER	
PEARSE, ADEPEJU OMOLOLA	
ART UNIT	**PAPER NUMBER**
1761	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/636,156	SIGNORINO ET AL.	
	Examiner	Art Unit	
	Adepeju Pearse	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The use of the trademark "MARCOAT" and "EMCOAT" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al (U.S. Pat. No. 4,725,441) in view of Cook (U.S. Pat. No. 5,567,438) and Signorino et al (U.S. Pat. No. 5,059, 248)

With regard to claims 1, 4 and 5, Porter et al disclose a maltodextrin coating suitable for a pharmaceutical, confectionery or food tablet (abstract). The coating comprises a plasticizer to make the maltodextrin non-brittle and non-cracking. The maltodextrin is a hydrolyzed starch, the carbohydrate composition having a DE of less than 20, which encompasses applicant's recited range (col 2 lines 40-49). However, Porter et al failed to disclose shellac in aqueous solution. Cook teaches an aqueous-based shellac dispersion to coat substrates such as food and medications in order to improve their appearance (col 2 lines 14-15). It would have been obvious to one of ordinary skill in the art to modify Porter et al with Cook by adding an aqueous shellac solution to the coating composition of Porter et al in order to improve the appearance of food or medications. With regard to claims 2-3, Porter et al failed to disclose a ratio of shellac to hydrolyzed starch. However, it would be expected that the ratio will be as disclosed by the applicant in order to provide a coating that has improved appearance because hydrolyzed starch alone produces a film coating which is brittle and cracks (col 4 lines 14-16). With regard to claims 6 and 7, Porter et al failed to disclose a concentration for shellac in the aqueous solution.

However, Cook teaches a concentration of about 26% (col 4 lines 17-18). It would have been obvious to expect that this concentration is not patentably distinct from that of applicant's recited concentration because about 25% could be higher or lower than 25%. With regard to claims 8-15 and 22, Porter et al disclose suitable plasticizers including polyethylene glycol 400, 3350, and 8000, triacetin, triethylcitrate, glycerine and propylene glycol (col 2 lines 55-60). The plasticizers are used in a range of 3.5 to 15% by weight of the coating mixture (col 2 lines 60-63); this range encompasses applicant's recited range. With regard to claims 16-21, Porter et al disclose that pigments can be added to the coating composition in a range of 0 to 20% by weight of the mixture (col 3 lines 20-25). This range encompasses applicant's recited range. The pigments may include any approved by the FDA including FD &C lakes, D & C lakes, titanium dioxide and soluble dyes (col 3 lines 25-33). With regard to claims 23-24, Porter et al discloses that a coating dispersion of 15 parts solids is preferred but, a mixture of 25 to 30 parts solid is workable for spray coating (col 2 lines 8-11). This range encompasses applicant's recited range. With regard to claim 25, the rejection and reference is cited as applied to claim 1 above, Porter et al failed to disclose adding ethylene diamine tetraacetic acid salt to the coating composition. However, Signorino et al teach an improved stable fluid aqueous dispersion composition comprising a plasticizer, a film coating resin such as shellac and a salt such as ethylene diamine tetraacetic acid as a stabilizing agent (abstract). It would have been obvious to one of ordinary skill in the art to modify Porter et al with Cook as stated above and Signorino et al to incorporate ethylene diamine tetraacetic acid salt as a stabilizing agent. With regard to claims 26-28, Porter failed to disclose the amount of solids and concentration of ethylene diamine tetraacetic acid. However, Signorino et al teach an aqueous dispersion containing approximately 25 to 40 wt % solids, and a

concentration of approximately 0.5 to 3.5-wt% of the salt such as tetrasodium ethylene diamine tetraacetic acid in the coating composition (col 2 lines 62-67, see example 1). It would have been obvious to modify Porter et al with Signorino et al in order to have an effective amount of the stabilizing agent in the coating composition. With regard to claims 29-34, the rejections and references are cited as stated above. The applied references combined have disclosed a coating composition with similar ingredients and ranges within applicant's cited ranges for each ingredient. It is a matter of design choice whether FD & C red 40 or FD & C yellow 5 is utilized based on preference.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. References contain similar subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adepeju Pearse whose telephone number is 571-272-8560. The examiner can normally be reached on Monday through Friday, 8.00am - 4.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peju Pearse
Art Unit 1761

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